

**SECTION 5 – 510(k) SUMMARY**  
***Sarns™ Soft-Flow® Aortic Cannula***

**FEB 18 2014**

Date Prepared: August 2013

**Sponsor Information:**

Owner/Applicant/Submitter: Terumo Cardiovascular Systems Corporation  
6200 Jackson Road  
Ann Arbor, Michigan 48103  
Phone: 1-800-262-3304  
Fax: 410-398-6079  
Registration No. 1828100

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**Device Names/Classifications:**

Device Trade Name: Sarns™ Soft-Flow® Aortic Cannula  
Device Common Name: Aortic cannula for cardiopulmonary bypass  
Classification Name: Cardiopulmonary bypass vascular catheter, cannula, tubing  
Regulation Number: 21 CFR 807.4210  
Classification: Class II  
Product Code: DWF

**Predicate Devices:**

- Sarns™ Low Jetting Aortic Arch Cannula, K934127
- Sarns™ Xcoated Cannula, K083301
- Medtronic Select 3D® Arterial Cannula, 18 Fr, K043179
- Medtronic Select 3D® Arterial Cannula, 24 Fr, K033416

**Purpose of Submission:**

Terumo Cardiovascular Systems is submitting this Premarket Notification due to cumulative changes that have been made since the time that the original submissions were cleared by FDA. Although none of the individual changes were determined to be significant, Terumo Cardiovascular Systems Corporation believes it is appropriate to submit a 510(k) that represents the devices in their current design state.

***Intended Use/Indications for Use:***

The Sarns™ Soft-Flow® Aortic Cannula is indicated for perfusion of the ascending aorta during cardiopulmonary bypass surgery for up to 6 hours of use.

***Principles of Operation and Technology:***

The subject devices are modifications of the predicate devices, and these modifications do not impact the technology of the predicate devices, the principles of operation and do not raise different or new questions of safety and effectiveness from the predicates. The Sarns™ Soft-Flow® Aortic Cannula provides a conduit for the flow of patient blood within the extracorporeal circuit during cardiopulmonary bypass surgery. Typically, blood is gravity drained from the body into a blood reservoir. From the reservoir, blood then is propelled through the balance of the extracorporeal circuit via a roller pump or centrifugal pump. The Sarns™ Soft-Flow® Aortic Cannula is a component within the circuit that tunnels patient blood back into the body.

***Design and Materials:***

The design of the Sarns™ Soft-Flow® Aortic Cannula allows patient blood to re-enter the body after the blood has routed through an extracorporeal circuit for blood oxygenation. The design of the cannula is simple in that it consists of a tubular conduit with a tip that can be positioned into the patient's anatomy (ascending aorta) to allow the blood to re-enter the vascular blood stream.

The materials of construction for the Sarns™ Soft-Flow® Aortic Cannula can include polyvinylchloride, PMEA polymer, polyethylene, acrylonitrile butadiene styrene and stainless steel.

***Performance Evaluations:***

Clinical studies involving patients are not necessary to demonstrate the safety and effectiveness of the subject devices. Performance assessments for safety and effectiveness were accomplished through bench studies that included the following evaluations:

- force at break
- liquid and air leak
- ink adhesion
- hemolysis
- pressure drop
- exit velocity

***Substantial Equivalence Comparison:***

The information presented in this section depicts a comparison between the subject device, the modified Sarns™ Soft-Flow® Aortic Cannula and the predicate device, the unmodified Sarns™ Soft-Flow® Aortic Cannula.

- ***Comparison of Intended Use:***

The modified Sarns™ Soft-Flow® Aortic Cannula and the predicate Sarns™ Soft-Flow® Aortic Cannula have the exact same intended use statements:

The modified and the unmodified Sarns™ Soft-Flow® Aortic Cannulae are each indicated for perfusion of the ascending aorta during cardiopulmonary bypass surgery for up to 6 hours of use.

- ***Duration of Use:***

The modified Sarns™ Soft-Flow® Aortic Cannula and the predicate Sarns™ Soft-Flow® Aortic Cannula can both be used in procedures lasting up to 6 hours in duration.

- ***Comparison of Labeling:***

The labeling that will be used for the modified device is similar to the labeling used with the predicate device, although some labeling is revised to provide greater clarity for the user. The revised *instructions* labeling accurately presents the directions that are necessary for the end-user to employ the device in a safe and effective manner. Terumo submits that the labeling complies with applicable regulations in those regions where the device is to be distributed.

- ***Comparison of Operation and Technology:***

The modified Sarns™ Soft-Flow® Aortic Cannula and the predicate Sarns™ Soft-Flow® Aortic Cannula utilize the exact same technologies and principles of operation. The technology of the modified Cannula is not impacted by the modifications made to the subject device.

- ***Comparison of Design:***

With respect to the design of the modified Sarns™ Soft-Flow® Aortic Cannula, there have been no significant design changes implemented. Terumo has made *non-significant* changes since the original submission of these devices – each of which has been determined to maintain the integrity of the product without adversely impacting safety and/or performance.

- ***Comparison of Materials:***

The materials of construction used in the modified Sarns™ Soft-Flow® Aortic Cannula are the same generic materials that are used in the predicate device. The only difference between the subject and predicate devices is a luer cap manufactured with acrylonitrile butadiene styrene, and the predicate device luer cap was manufactured with polypropylene.

- ***Comparison of Performance:***

Terumo Cardiovascular has conducted performance studies with the modified devices to ensure that they all continue to satisfy appropriate device performance specifications and to ensure that they satisfy customer needs. There are no appreciable differences between the subject devices and the predicate devices.

***Conclusion:***

The information and data included in the 510(k) notice demonstrate the Sarns™ Soft-Flow Aortic Cannula is *substantially equivalent* to the predicate devices for perfusion of the ascending aorta during cardiopulmonary bypass for up to 6 hours of use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

February 18, 2014

Terumo Cardiovascular Systems Corporation  
Eileen Dorsey, Regulatory Affairs Manager  
125 Blue Ball Road  
Elkton, MD 21921

Re: K132451

Trade Name: Sarns™ Soft Flow Aortic Cannula  
Regulation Number: 21 CFR 870.4210  
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing  
Regulatory Class: Class II  
Product Code: DWF  
Dated: January 13, 2014  
Received: January 14, 2014

Dear Ms. Dorsey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



SECTION 4 – INDICATION FOR USE  
*Sarns™ Soft-Flow® Aortic Cannula*

510(k) Number (if known): K132451  
Unknown at time of submission

Device Name: Sarns™ Soft-Flow® Aortic Cannula

**Indications for Use:**

Device Intended Use - The device is indicated for perfusion of the ascending aorta during cardiopulmonary bypass surgery for up to six hours of use.

Prescription Use   X   or Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*M. S. Hillman*